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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/581,352	06/09/2000	JAN STERNBY	GAMBRO-3.3-246	9945

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EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1743	7

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

eb7

Office Action Summary	Application No.	Applicant(s)	
	09/581,352	STERNBY, JAN	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 13-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 13-21 and 23-26 is/are rejected.

7)☒ Claim(s) 22 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4, 5.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. Claims 15-19 and 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 8 of claim 15, the phrase "said body" lacks antecedent basis.

In claim 16, the "second predetermined substance" is indefinite and vague since it is unclear whether this second substance is different from the recited predetermined substance in the blood of the mammal recited in claim 13. Is the disturbance in the dialyser a change in the concentration of a substance in the dialysis fluid which is different from the substance whose concentration in the blood of a mammal it is desired to calculate? See this same problem with the second predetermined substance in claims 17, 18, 19, 23, 24, 25 and 26.

On lines 5-6 of claim 17, the phrase "said predetermined substance" should be changed to –said second predetermined substance--.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 13-14 and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Sternby (EP 547,025).

Sternby teaches of a dialysis system and method for determining the concentration of a predetermined substance in the blood of a mammal, such as sodium ion concentration. The

method comprises the steps of passing blood on one side of a semipermeable membrane in a dialyser and circulating a dialysis fluid on the other side of the semipermeable membrane. The concentration of the predetermined substance, such as sodium ions, is then calculated in the dialysate resulting from the passage of sodium ions from the blood through the semipermeable membrane into the dialysis fluid. A disturbance is then caused in the dialyser, such as a change in the concentration of sodium ions originally present in the dialysis fluid. The effect of the disturbance is determined by measuring the concentration of the sodium ions both upstream and downstream of the dialyser. The effective dialysance of the dialyser is then obtained from a comparison of the conductivity of the dialysis fluid both before and after the dialyser respectively. The effective dialysance (K) is used in the equation to calculate the concentration of the predetermined substance (i.e. sodium ions) in the original untreated sample of blood analyzed. In addition, this equation also utilizes the flow rate of the dialysis liquid. See the equation in column 3 and claims 1-7 of Sternby.

5. Claims 13 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Goux et al. (US Patent no. 5,567,320, submitted in the Information Disclosure Statement filed on June 9, 2000).

Goux et al teach of a method for determining a significant parameter of a blood sample undergoing a dialysis blood treatment, such as the concentration of sodium ions in the original sample of blood. The method comprises the steps of passing blood on one side of a semipermeable membrane in a dialyser and circulating a dialysis fluid on the other side of the semipermeable membrane. The concentration of the predetermined substance, such as sodium ions, is then measured in the dialysate resulting from the passage of sodium ions from the blood

sample through the semipermeable membrane into a first dialysis fluid. A disturbance is then caused in the system in the form of passing a second and third dialysis fluid through the system having a different initial concentration of sodium ions. The concentration of the sodium ions in each of the dialysis fluids is measured both upstream and downstream of the dialyser. The effective dialysance of the dialyser is then calculated using the various measured concentrations of the sodium ions both upstream and downstream of the dialyser, and the flow rate of the dialysate. Lastly, the concentration of the predetermined substance (i.e. sodium ions) in the original blood sample analyzed upstream of the dialyser is calculated based upon the effective dialysance. The clearance of the dialyser for urea in the original blood sample can also be determined from the calculated real dialysance of the dialyser for sodium. See column 5 and the claims in Goux et al.

6. Claims 15-19 and 23-26 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests determining the effective dialysance of a dialyser by changing the concentration of a second substance in the dialysis fluid, wherein the second substance is different from the first predetermined substance whose concentration is being measured in the original blood sample analyzed, and determining the effective dialysance from the resulting change in the concentration of the second substance.

7. Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims for the same reasons as given above.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Goux et al (US Patent nos. 6,110,384 and 5,399,157), Sternby (US Patent no. 5,024,756), Bene, Goldau et al, Polaschegg et al and Goldau who all teach of different dialysis systems and methods.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

February 18, 2004

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700